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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,523	07/15/2002	Shigeo Takada	P22165	2401

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EXAMINER	
WELLS, LAUREN Q	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,523	TAKADA ET AL.	
	Examiner	Art Unit	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *4,9 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-8,10,11 and 13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/12/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-17 are pending. Claims 4, 9 and 12 are withdrawn from consideration, as they are directed toward non-elected subject matter. The Preliminary Amendment filed 3/29/02, amended claims 5, 6 and 8, and added claims 10-17.

Lack of Unity Requirement

Applicant's election with traverse of Group I in the Response filed 12/4/03 is acknowledged. The traversal is on the ground(s) that there should be no undue burden to examine each of the groups of the invention. This is not found persuasive. Groups I, II, and III are not related by a special technical feature and are directed toward distinct inventions. Thus, a search of all three inventions would place an undue burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-8, 10-11, 13-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/466541; 10/451786; 10/070434; 10/181421; 10/070435;

10/451787. Although the conflicting claims are not identical, they are not patentably distinct from each. First, it is respectfully pointed out that the preamble and the intended use recitations of the instant claims and those of the above referenced product claims are not afforded patentable weight. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Additionally, the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, regarding the product by process claims of the instant Application, it is respectfully pointed out that a product-by-process claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113.

Thus, since the instant claims and the above referenced application claims, all recite an agent comprising a mixture of cyclic and/or straight chain poly lactic acids having a condensation degree of 3 to 19, though the agents are recited for different intended uses, the instant claims are obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 11 and 14 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for improving obesity, does not reasonably provide enablement for preventing obesity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention provides a mixture of cyclic and/or straight chain poly lactic acids having a condensation degree of 3 to 19 as an active ingredient for treating/improving obesity.

(2) The state of the prior art

The prior art teaches lactic acid as an agent that is known for treating obesity. However, the prior art does not teach an agent for preventing obesity. See Japanese abstract 05255097.

(3) The relative skill of those in the art

The relative skill of the those in the art is high, as administering in vivo pharmaceutical agents that have unique physiological pathways in the body and following the in vivo and ex vivo effects of the agents is very complicated and time consuming.

(4) The predictability or unpredictability of the art

The unpredictability of the pharmaceutical art of obesity is very high. It is unknown what factures cause obesity, physical, psychological, and/or environmental factors, and how the physical factures are manifested in vivo, i.e., at the level of gene, cell, signaling factor. . . Thus, matching a pharmaceutical agent with a physiological effect for reducing obesity is very unpredictable.

(5) The breadth of the claims

The claims are very broad. The poly lactic acids can contain from 3 to 19 lactic acid units, wherein the units can be any combination of D or L lactic acids, can be in straight or cyclic configurations, and the agents can contain an unlimited number of other ingredients, per the open-ended "comprising" language.

(6) The amount of direction or guidance presented

The instant specification provides no guidance or direction as to how the instant invention prevents obesity. The instant specification merely states that the instant invention prevents obesity without providing any evidence of such a statement. The instant examples are directed toward appetite suppressing agents and basal metabolism promoting agents that improve obesity, but nowhere are there examples of preventing obesity.

Furthermore, preventing obesity is inconsistent with what is known in the art since (1) reduction of obesity indicates that obesity is decreased, but not prevented; and (2) elimination of obesity indicates that symptoms of obesity may occur. Furthermore, prevention of obesity indicates that the subject *never* experiences any characteristics associated with obesity. Hence, the amount of guidance present in the specification, the absence of data indicating that the symptoms of obesity do not occur when poly lactic acids of 3-19 condensation degree are administered, and the state of the prior art indicating that the treatment using lactic acid is possible, all indicate that treatment, not prevention of obesity is possible.

It is further respectfully pointed out that the significance of particular pharmaceutical agents for different aspects of biological activity cannot be predicted a priori but must be determined from the case to case by painstaking experimental study.

(7) The presence or absence of working examples

As stated above, the instant specification provides working examples, but these working examples are directed toward the improvement/treatment of obesity, and not the prevention of obesity..

(8) The quantity of experimentation necessary

Since the significance of particular pharmaceutical agents, such as poly lactic acids, for different aspects of biological activity cannot be predicted a priori but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine the all of the cyclic and/or straight chain poly lactic acids with a condensation number of 3-19 that prevent obesity.

In summary, the amount of guidance necessary to perform Applicant's invention would result in undue experimentation because the skilled artisan would be forced to randomly test numerous conditions, amounts, and chemical formulas of poly lactic acids in composition to determine what poly lactic acid compositions prevents obesity. Hence, the amount of guidance present in the specification fails to present the necessary instruction such that one can readily determine the appropriate agents of claims 3, 11, and 14.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-8, 10-11, 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Naganushi et al. (JP abstract 10130153 A).

Naganushi et al. disclose an agent comprising a cyclic and straight chain mixed poly L-lactic acid having 3-19 degree of condensation as a main component, obtained by dehydrating and condensing L-lactic acid in a nitrogen gas atmosphere (inactive atmosphere) by reduction in pressure and heating by stages to give a reaction solution, drying soluble components of the reaction solution with ethanol and methanol under reduced pressure, carrying out a reversed phase ODS column chromatography, eluting the absorbed substance with a 25-50% aqueous solution of acetonitrile at pH2.0 and collecting a fraction prepared by elution with 100% acetonitrile at pH 2.0.

The Examiner respectfully points out instant claims 6-8, 13-17 are product-by-process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113.

It is respectfully pointed out that the recitations "appetite suppressing agent", "basal metabolism promoting agent", and "an agent for improving and/or preventing obesity", have not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

The term "consists substantially" in the instant claims is taken to mean that L-lactic acid units in the mixture of poly lactic acids are at least 70%, per the definition on pages 8-9 of the instant specification.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is 571-272-0634. The examiner can normally be reached on M&R (5:30-4).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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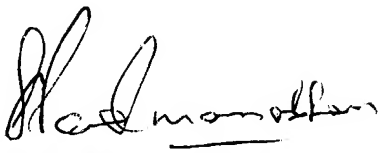

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